



FORM PTO/A-149/A (modified PTO/SB/08)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICATION NO.: 10/644,052 ATTY. DOCKET NO.: C1037.70048US00

FILING DATE: August 19, 2003 CONFIRMATION NO.: 4791

APPLICANT: Arthur M. Krieg et al.

GROUP ART UNIT: 1645 EXAMINER: N. Archie

Sheet of

U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		5,527,899		Froehler	06-18-1996
		5,679,647		Carson et al.	10-21-1997
		5,929,226		Padmapriya et al.	07-27-1999
		6,031,086		Switzer	02-29-2000
		6,121,434		Peyman et al.	09-19-2000
		6,348,312	B1	Peyman et al.	02-19-2002
		6,426,334	B1	Agrawal et al.	07-30-2002
		6,476,000	B1	Agrawal et al.	11-05-2002
		6,498,148	B1	Raz	12-24-2002
		6,534,062	B1	Raz et al.	03-18-2003
		6,605,708	B1	Habus et al.	08-12-2003
		6,815,429	B2	Agrawal	11-09-2004
		6,977,245	B2	Klinman et al.	12-20-2005
		7,105,495	B2	Agrawal et al.	09-12-2006
		2002-0137714	A1	Kandamilla et al.	09-26-2002
		2003-0060440	A1	Klinman et al.	03-27-2003
		2003-0133988	A1	Fearon et al.	07-17-2003
		2003-0175731	A1	Fearon et al.	09-18-2003
		2003-0186912	A1	Agrawal	10-02-2003
		2004-0006034	A1	Raz et al.	01-08-2004
		2004-0058883	A1	Phillips et al.	03-25-2004
		2004-0092468	A1	Schwartz et al.	05-13-2004
		2004-0097719	A1	Agrawal et al.	05-20-2004
		2004-0132677	A1	Fearon et al.	07-08-2004
		2004-0136948	A1	Fearon et al.	07-15-2004
		2005-0130918	A1	Agrawal et al.	06-16-2005
		2006-0019909	A1	Agrawal et al.	01-26-2006
		2006-0074040	A1	Kandimalla et al.	04-06-2006
		2006-0211641	A1	Agrawal et al.	09-21-2006
		2006-0217328	A1	Kandimalla et al.	09-28-2006
		2006-0287261	A1	Agrawal et al.	12-21-2006

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
		EP	0 468 520	A2	Mitsui Toatsu Chemicals, Inc.	01-29-1992	

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
		WO	98/11211	A2	Hybridon et al.	03-19-1998	
		WO	98/49288	A1	Hybridon Inc.	11-05-1998	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		AGRAWAL et al., Pharmacokinetics of oligonucleotides. Ciba Found Symp. 1997;209:60-75; discussion 75-8.	
		AGRAWAL et al., Absorption, tissue distribution and in vivo stability in rats of a hybrid antisense oligonucleotide following oral administration. Biochem Pharmacol. 1995 Aug 8;50(4):571-6.	
		AGRAWAL et al., In vivo pharmacokinetics of phosphorothioate oligonucleotides containing contiguous guanines. Antisense Nucleic Acid Drug Dev. 1997 Jun;7(3):245-9.	
		AGRAWAL et al., Antisense therapeutics: is it as simple as complementary base recognition? Mol Med Today. 2000 Feb;6(2):72-81.	
		AGRAWAL et al., Medicinal chemistry and therapeutic potential of CpG DNA. Trends Mol Med. 2002 Mar;8(3):114-21.	
		AGRAWAL et al., Pharmacokinetics of antisense oligonucleotides. Clin Pharmacokinet. 1995 Jan;28(1):7-16.	
		BALLAS et al., Induction of NK activity in murine and human cells by CpG motifs in oligodeoxynucleotides and bacterial DNA. J Immunol. 1996 Sep 1;157(5):1840-5.	
		BOGGS et al., Characterization and modulation of immune stimulation by modified oligonucleotides. Antisense Nucleic Acid Drug Dev. 1997 Oct;7(5):461-71.	
		BRANDA et al., Immune stimulation by an antisense oligomer complementary to the rev gene of HIV-1. Biochem Pharmacol. 1993 May 25;45(10):2037-43.	
		BROIDE et al., Modulation of asthmatic response by immunostimulatory DNA sequences. Springer Semin Immunopathol. 2000;22(1-2):117-24.	
		CHATURVEDI et al., Stabilization of triple-stranded oligonucleotide complexes: use of probes containing alternating phosphodiester and stereo-uniform cationic phosphoramidate linkages. Nucleic Acids Res. 1996 Jun 15;24(12):2318-23.	
		COHEN, Selective anti-gene therapy for cancer: principles and prospects. Tohoku J Exp Med. 1992 Oct;168(2):351-9.	
		COLEY Pharmaceutical Group, Press Release, January 22, 2007, Coley Pharmaceutical Group Updates Hepatitis C Drug Development Strategy	
		COLEY Pharmaceutical Group, Press Release, June 20, 2007, Coley Pharmaceutical Group Announces Pfizer's Discontinuation of Clinical Trials for PF-3512676 Combined with Cytotoxic Chemotherapy in Advanced Non Small Cell Lung Cancer	
		CROOKE et al., Phosphorothioate Oligonucleotides. Therapeut Apps. 1995;ch5:63-84.	
		CROOKE et al., Progress in antisense oligonucleotide therapeutics. Annu Rev Pharmacol Toxicol. 1996;36:107-29.	
		EQUILS et al., Toll-like receptor 2 (TLR2) and TLR9 signaling results in HIV-long terminal repeat trans-activation and HIV replication in HIV-1 transgenic mouse spleen cells: implications of simultaneous activation of TLRs on HIV replication. J Immunol. 2003 May 15;170(10):5159-64.	
		FIELDS et al., Fields' Virology. 2001;1:1153.	
		FILION et al., Development of immunomodulatory six base-length non-CpG motif oligonucleotides for cancer vaccination. Vaccine. 2004 Jun 23;22(19):2480-8.	
		HADDEN et al., Immunostimulants. Trends Pharmacol Sci. 1993 May;14(5):169-74.	
		HAHM et al., Efficacy of polyadenylic polyuridylic acid in the treatment of chronic active hepatitis B. Int J Immunopharmacol. 1994 Mar;16(3):217-25.	
		HARTMANN et al., Delineation of a CpG phosphorothioate oligodeoxynucleotide for activating primate immune responses in vitro and in vivo. J Immunol. 2000 Feb 1;164(3):1617-24.	

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		HENRY et al., Chemically modified oligonucleotides exhibit decreased immune stimulation in mice. <i>J Pharmacol Exp Ther</i> . 2000 Feb;292(2):468-79.	
		HSIEH et al., Incorporation of CpG oligodeoxynucleotide fails to enhance the protective efficacy of a subunit vaccine against <i>Mycobacterium tuberculosis</i> . <i>Vaccine</i> . 2004 Jan 26;22(5-6):655-9.	
		HYBRIDON, Press Release, Hybridon Shows Immunomodulatory Activity of Synthetic Oligonucleotides. 2001 May 7	
		JAIN et al., CpG-oligodeoxynucleotides inhibit airway remodeling in a murine model of chronic asthma. <i>J Allergy Clin Immunol</i> . 2002 Dec;110(6):867-72.	
		JAIN et al., The promise of CpG DNA in the treatment of asthma. <i>Recent Res Develop Resp Crit Care Med</i> . 2002;2:7-18.	
		JIANG et al., Enhancing immunogenicity by CpG DNA. <i>Curr Opin Mol Ther</i> . 2003 Apr;5(2):180-5.	
		JURK et al., C-Class CpG ODN: sequence requirements and characterization of immunostimulatory activities on mRNA level. <i>Immunobiology</i> . 2004;209(1-2):141-54.	
		KANDIMALLA et al., Effect of chemical modifications of cytosine and guanine in a CpG-motif of oligonucleotides: structure-immunostimulatory activity relationships. <i>Bioorg Med Chem</i> . 2001 Mar;9(3):807-13.	
		KANDIMALLA et al., A dinucleotide motif in oligonucleotides shows potent immunomodulatory activity and overrides species-specific recognition observed with CpG motif. <i>Proc Natl Acad Sci U S A</i> . 2003 Nov 25;100(24):14303-8. Epub 2003 Nov 10.	
		KANDIMALLA et al., Towards optimal design of second-generation immunomodulatory oligonucleotides. <i>Curr Opin Mol Ther</i> . 2002 Apr;4(2):122-9.	
		KANDIMALLA et al., Divergent synthetic nucleotide motif recognition pattern: design and development of potent immunomodulatory oligodeoxyribonucleotide agents with distinct cytokine induction profiles. <i>Nucleic Acids Res</i> . 2003 May 1;31(9):2393-400.	
		KITAGAKI et al., Immunomodulatory effects of CpG oligodeoxynucleotides on established th2 responses. <i>Clin Diagn Lab Immunol</i> . 2002 Nov;9(6):1260-9.	
		KLINE et al., Modulation of airway inflammation by CpG oligodeoxynucleotides in a murine model of asthma. <i>J Immunol</i> . 1998 Mar 15;160(6):2555-9.	
		KLINE et al., Treatment of established asthma in a murine model using CpG oligodeoxynucleotides. <i>Am J Physiol Lung Cell Mol Physiol</i> . 2002 Jul;283(1):L170-9.	
		KLINE et al., DNA therapy for asthma. <i>Curr Opin Allergy Clin Immunol</i> . 2002 Feb;2(1):69-73.	
		KLINMAN et al., Immunotherapeutic applications of CpG-containing oligodeoxynucleotides. <i>Drug News Perspect</i> . 2000 Jun;13(5):289-96.	
		KLINMAN et al., CpG motifs present in bacteria DNA rapidly induce lymphocytes to secrete interleukin 6, interleukin 12, and interferon gamma. <i>Proc Natl Acad Sci U S A</i> . 1996 Apr 2;93(7):2879-83.	
		KNIFE et al., eds., <i>Fields' Virology</i> . 2001;1:1004-16.	
		KRIEG et al., Lymphocyte activation mediated by oligodeoxynucleotides or DNA containing novel unmethylated CpG motifs. American College of Rheumatology 58 th National Scientific Meeting. Minneapolis, Minnesota, October 22, 1994. Abstracts. <i>Arthritis Rheum</i> . 1994 Sep;37(9 Suppl).	
		KRIEG et al., Causing a commotion in the blood: immunotherapy progresses from bacteria to bacterial DNA. <i>Immunol Today</i> . 2000 Oct;21(10):521-6.	
		KRIEG et al., P-chirality-dependent immune activation by phosphorothioate CpG oligodeoxynucleotides. <i>Oligonucleotides</i> . 2003;13(6):491-9.	
		KRIEG, Immune effects and mechanisms of action of CpG motifs. <i>Vaccine</i> . 2001 Nov 8;19(6):618-22.	
		KRIEG et al., Chapter 17:Immune stimulation by oligonucleotides. in <i>Antisense Drug Tech</i> . 2001;1394:471-515.	
		KRIEG, The role of CpG motifs in innate immunity. <i>Curr Opin Immunol</i> . 2000 Feb;12(1):35-43.	
		KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. <i>Proc Natl Acad Sci U S A</i> . 1998 Oct 13;95(21):12631-6.	
		KRIEG, Therapeutic potential of Toll-like receptor 9 activation. <i>Nat Rev Drug Discov</i> . 2006 Jun;5(6):471-84.	

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		KRIEG et al., Induction of systemic TH1-like innate immunity in normal volunteers following subcutaneous but not intravenous administration of CPG 7909, a synthetic B-class CpG oligodeoxynucleotide TLR9 agonist. <i>J Immunother.</i> 2004 Nov-Dec;27(6):460-71.	
		KURAMOTO et al., Induction of T-cell-mediated immunity against MethA fibrosarcoma by intratumoral injections of a bacillus Calmette-Guerin nucleic acid fraction. <i>Cancer Immunol Immunother.</i> 1992;34(5):283-8.	
		LEE et al., An oligonucleotide blocks interferon-gamma signal transduction. <i>Transplantation.</i> 1996 Nov 15;62(9):1297-301.	
		LEE et al., CpG motif in synthetic ODN primes respiratory burst of olive flounder <i>Paralichthys olivaceus</i> phagocytes and enhances protection against <i>Edwardsiella tarda</i> . <i>Dis Aquat Organ.</i> 2003 Aug 15;56(1):43-8.	
		MACKELLAR et al., Synthesis and physical properties of anti-HIV antisense oligonucleotides bearing terminal lipophilic groups. <i>Nucleic Acids Res.</i> 1992 Jul 11;20(13):3411-7.	
		MUTWIRI et al., Strategies for enhancing the immunostimulatory effects of CpG oligodeoxynucleotides. <i>J Control Release.</i> 2004 May 31;97(1):1-17.	
		PARRONCHI et al., Phosphorothioate oligodeoxynucleotides promote the in vitro development of human allergen-specific CD4+ T cells into Th1 effectors. <i>J Immunol.</i> 1999 Dec 1;163(11):5946-53.	
		PAUL et al., Technology evaluation: CpG-7909, Coley. <i>Curr Opin Mol Ther.</i> 2003 Oct;5(5):553-9.	
		PAVLICK et al., Novel therapeutic agents under investigation for malignant melanoma. <i>Expert Opin Investig Drugs.</i> 2003 Sep;12(9):1545-58.	
		PISETSKY et al., Influence of backbone chemistry on immune activation by synthetic oligonucleotides. <i>Biochem Pharmacol.</i> 1999 Dec 15;58(12):1981-8.	
		PISETSKY, The influence of base sequence on the immunostimulatory properties of DNA. <i>Immunol Res.</i> 1999;19(1):35-46.	
		RANKIN et al., CpG motif identification for veterinary and laboratory species demonstrates that sequence recognition is highly conserved. <i>Antisense Nucleic Acid Drug Dev.</i> 2001 Oct;11(5):333-40.	
		ROTHENFUSSER et al., Recent advances in immunostimulatory CpG oligonucleotides. <i>Curr Opin Mol Ther.</i> 2003 Apr;5(2):98-106.	
		SATO et al., Immunostimulatory DNA sequences necessary for effective intradermal gene immunization. <i>Science.</i> 1996 Jul 19;273(5273):352-4.	
		SATOH et al., The study of mechanisms in CpG oligodeoxynucleotides-induced aggravation in murine allergic contact dermatitis to 2,4-dinitrofluorobenzene. <i>Fukushima Igaku Zasshi.</i> 2002;52(3):237-50. Abstract only.	
		SESTER et al., Phosphorothioate backbone modification modulates macrophage activation by CpG DNA. <i>J Immunol.</i> 2000 Oct 15;165(8):4165-73.	
		STEIN et al., Problems in interpretation of data derived from in vitro and in vivo use of antisense oligodeoxynucleotides. <i>Antisense Res Dev.</i> 1994 Summer;4(2):67-9.	
		STEIN et al., Physicochemical properties of phosphorothioate oligodeoxynucleotides. <i>Nucleic Acids Res.</i> 1988 Apr 25;16(8):3209-21.	
		STEIN et al., Non-antisense effects of oligodeoxynucleotides. <i>Antisense Technology.</i> 1997; ch11: 241-64.	
		STEIN et al., Antisense oligonucleotides as therapeutic agents—is the bullet really magical? <i>Science.</i> 1993 Aug 20;261(5124):1004-12.	
		THREADGILL et al., Mitogenic synthetic polynucleotides suppress the antibody response to a bacterial polysaccharide. <i>Vaccine.</i> 1998 Jan;16(1):76-82.	
		TOKUNAGA et al., A synthetic single-stranded DNA, poly(dG,dC), induces interferon-alpha/beta and -gamma, augments natural killer activity, and suppresses tumor growth. <i>Jpn J Cancer Res.</i> 1988 Jun;79(6):682-6.	
		VAN UDEN et al., Immunostimulatory DNA and applications to allergic disease. <i>J Allergy Clin Immunol.</i> 1999 Nov;104(5):902-10.	
		VOLLMER et al., Characterization of three CpG oligodeoxynucleotide classes with distinct immunostimulatory activities. <i>Eur J Immunol.</i> 2004 Jan;34(1):251-62.	
		VOLLMER et al., Modulation of CpG oligodeoxynucleotide-mediated immune stimulation by locked nucleic acid (LNA). <i>Oligonucleotides.</i> 2004 Spring;14(1):23-31.	

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		YAMAMOTO et al., Lipofection of synthetic oligodeoxyribonucleotide having a palindromic sequence of AACGTT to murine splenocytes enhances interferon production and natural killer activity. Microbiol Immunol. 1994;38(10):831-6.	
		YAMAMOTO et al., Ability of oligonucleotides with certain palindromes to induce interferon production and augment natural killer cell activity is associated with their base length. Antisense Res Dev. 1994 Summer;4(2):119-22.	
		YAMAMOTO et al., Oligodeoxyribonucleotides with 5'-ACGT-3' or 5'-TCGA-3' sequence induce production of interferons. Curr Top Microbiol Immunol. 2000;247:23-39.	
		YU et al., Accessible 5'-end of CpG-containing phosphorothioate oligodeoxynucleotides is essential for immunostimulatory activity. Bioorg Med Chem Lett. 2000 Dec 4;10(23):2585-8.	
		YU et al., Modulation of immunostimulatory activity of CpG oligonucleotides by site-specific deletion of nucleobases. Bioorg Med Chem Lett. 2001 Sep 3;11(17):2263-7.	
		ZHAO et al., Pattern and kinetics of cytokine production following administration of phosphorothioate oligonucleotides in mice. Antisense Nucleic Acid Drug Dev. 1997 Oct;7(5):495-502.	
		ZHAO et al., Immunostimulatory activity of CpG containing phosphorothioate oligodeoxynucleotide is modulated by modification of a single deoxynucleoside. Bioorg Med Chem Lett. 2000 May 15;10(10):1051-4. Abstract Only.	
		ZHU et al., Modulation of ovalbumin-induced Th2 responses by second-generation immunomodulatory oligonucleotides in mice. Int Immunopharmacol. 2004 Jul;4(7):851-62.	
		ZIMMERMANN et al., Immunostimulatory DNA as adjuvant: efficacy of phosphodiester CpG oligonucleotides is enhanced by 3' sequence modifications. Vaccine. 2003 Feb 14;21(9-10):990-5.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. __, filed __, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]